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**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF NEW JERSEY**

| | | |
|---|---|---|
| TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., and NORTON (WATERFORD) LTD., | : | Consolidated Civil Action No. 20-10172 (JXN)(MAH) |
| Plaintiffs, | : | |
| v. | : | |
| CIPLA LTD., AUROBINDO PHARMA LLC, AUROBINDO PHARMA USA, INC., and AUROLIFE PHARMA LLC, | : | |
| Defendants. | : | |

**PLAINTIFFS' OPENING CLAIM CONSTRUCTION BRIEF**

# Table of Contents

## Table of Authorities

### FEDERAL CASES

**STATUTES**



**OTHER AUTHORITIES**

## I. Introduction

This is a Hatch-Waxman case. Defendants Cipla and Aurobindo each filed Abbreviated New Drug Applications ("ANDAs") seeking to market copycat generic versions of Teva's QVAR® inhaler product before the expiration of Teva's Orange Book-listed patents. On the basis of those ANDA filings, Teva sued both Defendants for infringement.

Unable to defend against assertions that their products infringe Teva's patents as written, Defendants invite the Court to defy more than a century of consistent, controlling precedent by re-writing the asserted claims. Defendants ostensibly recognize their strained constructions' low odds of success and attempt to sow confusion by presenting this court with a remarkable *nineteen* manufactured disputes. None of Defendants' nineteen constructions has merit. But Defendants appear to be operating on the assumption that if one throws enough pitches, eventually a ball will be called a strike. Not so. Many of those disputes regard the meaning of simple, well-known, and commonly understood words. In fact, the terms identified by Defendants do not require construction—each can and should be afforded its plain meaning in the context of the surrounding and detailed claim language. Defendants' proposed constructions, which import into the claims limitations untethered to the claim language, violate both black-letter tenets of claim construction and common sense. They should be rejected.

## II. Background

The five Asserted Patents[1] relate to Teva's QVAR® product, which was FDA-approved to treat asthma. Defendants seek to market a metered-dose inhaler ("MDI") of QVAR®, prior to the expiration of Teva's patents covering the MDIs. Typically, an MDI contains a pressurized canister of medicine that fits into a plastic body with a mouthpiece. Familiarly, by pressing down on the medication canister, the patient causes the canister to dispense a pre-determined amount of medication, which the patient then inhales through the mouthpiece. For example, the patents' Figure 1 depicts (with highlighting added) the inhaler body (10) with a mouthpiece (16) and mouthpiece cap (14). From another perspective, the patents' Figure 7A shows a medication canister (20) inside the inhaler body.

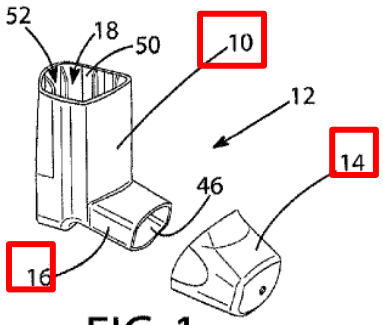


FIG. 1

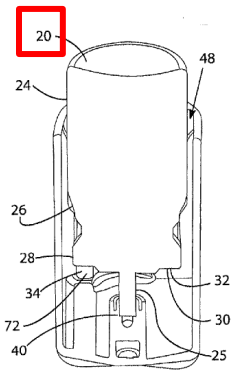


FIG. 7A

MDIs typically contain many doses of an inhalation medication. For example, the QVAR® MDIs contained 120 doses per canister. But unlike patients taking pills

[1] The Asserted Patents are Patent Nos. 9,463,289 ("the '289 Patent") (Ex. 1); 9,808,587 ("the '587 Patent") (Ex. 2); 10,086,156 ("the '156 Patent") (Ex. 3); 10,561,808 ("the '808 Patent") (Ex. 4); and 10,695,512 ("the '512 Patent") (Ex. 5).

from a bottle, patients using MDIs cannot not simply look at their inhaler and see how many doses are remaining. This presents a problem: For serious diseases like asthma, the consequences of believing, mistakenly, that an inhaler contains additional doses can be dire. Without a reliable way to track the number of doses dispensed and/or remaining, accidentally running out of medicine is a risky problem for asthma patients. FDA recognized this, and in 2003, issued guidance recommending that "manufacturers with metered-dose inhalers under development for oral inhalation integrate a dose-counting device into the development of their MDI drug product." Ex. 6 (FDA Guidance for Industry: Integration of Dose-Counting Mechanisms into MDI Drug Products), at 6.

This was no simple task. Dose counters must be scrupulously accurate. Indeed, an inaccurate dose counter is worse than no dose counter at all, since it provides the patient with a false sense of security. But designing a dose counter that records accurately every dose expended and does not increment inadvertently (for example when jostled) is quite a feat of engineering, especially when considering the small, portable nature of inhalers. To incorporate dose counters with the desired accuracy, engineers added dose counters to MDIs in the form of bulky, exterior-mounted components.

Teva's dose counter was a departure from this approach. As the Asserted Patents claim, Teva invented an accurate dose counter that can operate inside the

small confines of a traditional inhaler body. When the patient pushes downward on the medication canister to dispense medicine, the bottom surface of the medication canister interacts with a component of Teva's dose counter called the "actuation member" (described in detail below). The actuation member then transmits the canister's downward motion to the remaining components of the dose counter, which cause it to increment and indicate a count. Each of the five Asserted Patents share the same specification, but claim distinct, inventive aspects of Teva's novel dose counter designed to ensure counter accuracy within the small confines of a traditional inhaler body.

For example, the inventors recognized that by placing a dose counter into the inhaler body (rather than outside it, as other companies had done), the smaller scale of the dose counter's movements would require high precision to avoid miscounting. Moreover, Teva's inventors recognized, a dose counter *inside* the inhaler body could interact with the medication canister, undesirably, when the patient was not using the device. For instance, if the inhaler were carried in a backpack or dropped accidentally, the canister might rock and record a count even if no medication had been dispensed. This would reduce counter accuracy. To solve this problem, the inventors identified the kinds of rocking that were problematic, and created an inhaler body that would reduce this rocking by placing canister support rails in particular configurations. Specifically, Teva discovered that if the support rail of the

inhaler body were in a "common plane" with the actuation member (the part of the dose counter that interacts with the canister) and the center of the inhaler, undesired rocking could be reduced. The '289 Patent claims, *inter alia,* an inhaler with this advantageous configuration. The '587 Patent claims recite additional limitations requiring that the configuration "protects against unwanted actuation of the dose counter" or "protects against dose count errors."

The inventors also discovered that certain locations for the dose counter within the inhaler body were more advantageous—and facilitate more accurate counting—than others. In particular, the inventors recognized that it was advantageous to place the dose counter in a lower-than-expected position, so that a particular portion of the dose counter (the "actuator pawl") is below other components of the inhaler body (represented by a "datum plane" that passes through a "shoulder of a valve stem block") when the medication canister ejects medicine. The '156 Patent claims this unique and surprising configuration.

The '808 Patent reflects Teva's additional inventive refinement of its dose counter. To further ensure accuracy, Teva added a "regulator", which resists movement of the counter display to a small degree, thereby ensuring that the dose counter moves only in full-count increments. This further assists in preventing unwanted counts that might otherwise be experienced when, for example, the inhaler is dropped.

Finally, the '512 Patent, relates to a method of attachment for the dose counter to the inhaler body. By attaching the dose counter to the inhaler via a process known as "heat staking" on different sides of the dose counter chassis, the inventors ensured that the dose counter would be affixed in position firmly and accurately, avoiding unwanted movements.

Defendants seek to market copycat versions of QVAR® that take advantage of each of these inventions. To avoid the consequence of their infringement, Defendants rewrite Teva's claims by importing from the specification additional limitations the claims plainly do not recite. The law proscribes Defendants' transparent effort to deprive Teva of the full scope of its inventions.

## III. Legal Principles

Claim construction is the process by which the Court gives legal effect to the meaning of the claims. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 321-22 (2015). It is "not an obligatory exercise in redundancy" and is not required where a term's meaning is apparent from the claim language itself. *U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997); *Jazz Pharm., Inc. v. Amneal Pharm., LLC*, No. 13-391-ES-JAD, 2017 WL 5128748, at *11 (D.N.J. Nov. 6, 2017). Thus, a "threshold question to be addressed as part of a court's duty to undertake claim construction is whether and to what extent construction is even necessary." *Warner Chilcott Co. v. Mylan Inc.*, No. 11-6844-JAP, 2013 WL

3336872, at *3 (D.N.J. July 2, 2013).

Where, as here, there are no underlying factual questions in dispute, claim construction is a legal determination. *See Teva Pharm.*, 574 U.S. at 321.

In *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc), the Federal Circuit's leading *en banc* case setting forth the rubric that courts must follow in construing claims, the court instructed that the claim construction inquiry should proceed through a canonical hierarchy of sources: first the claims themselves, then the patent's specification, then the prosecution history, and finally any extrinsic evidence of record. To begin, "[i]t is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'" *Id.* at 1312 (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)). "[T]he claims themselves provide substantial guidance as to the meaning of particular claim terms" and "the context in which a term is used in the asserted claim can be highly instructive." *Id.* at 1314. This is true for the claim containing the disputed term itself, as well as all other claims in the patent—whether asserted or unasserted. *Id.* ("Other claims of the patent . . . can also be valuable sources of enlightenment as to the meaning of a claim term."). "For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Id.* at 1314-15. By the same token, courts should avoid

constructions that render a limitation in any claim "redundant," *id.* at 1324-25, or "superfluous," *Mformation Techs., Inc. v. Resch. in Motion Ltd.*, 764 F.3d 1392, 1399 (Fed. Cir. 2014).

"[T]he words of a claim 'are generally given their ordinary and customary meaning,'" which is "the meaning that the term would have to a person of ordinary skill in the art [("POSA")] in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Phillips*, 415 F.3d at 1312-13 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). There is a "heavy presumption" that "claim terms carry their full ordinary and customary meaning." *Epistar Corp. v. ITC*, 566 F. 3d 1321, 1334 (Fed. Cir. 2009). Thus, a patentee is "free to choose a broad term and expect to obtain the full scope of its plain and ordinary meaning." *Thorner v. Sony Comput. Ent. Am. LLC*, 669 F.3d 1362, 1367 (Fed. Cir. 2012). A court may depart from a term's ordinary and customary meaning in only two instances: lexicography or disavowal. *Toshiba Corp. v. Imation Corp.*, 681 F.3d 1358, 1369 (Fed. Cir. 2012); *Thorner*, 669 F.3d at 1365-66. "To act as its own lexicographer, a patentee must 'clearly set forth a definition of the disputed claim term' other than its plain and ordinary meaning," in the specification (usually) or prosecution history (rarely), and "must 'clearly express an intent' to redefine the term." *Thorner*, 669 F.3d at 1365 (quoting *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002); *Helmsderfer v.*

*Bobrick Washroom Equip, Inc.*, 527 F.3d 1379, 1381 (Fed. Cir. 2008)). Disavowal requires the specification or prosecution history to make "clear that the invention does not include a particular feature." *Id*. (quoting *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1341 (Fed. Cir. 2001)). That high bar is not met where "a prosecution argument is subject to more than one reasonable interpretation, one of which is consistent with a proffered meaning of the disputed term." *SanDisk Corp. v. Memorex Prods., Inc.*, 415 F.3d 1278, 1287 (Fed. Cir. 2005).

Beyond the claims themselves, "the specification 'is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.'" *Phillips*, 415 F.3d at 1315 (quoting *Vitronics*, 90 F.3d at 1582). But while the specification serves as a resource to understand the words that are used in the claims, courts must avoid the "cardinal sin" of importing language from the specification into the claims. *Id.* at 1320. The "law is clear that an applicant is not required to describe in the specification every conceivable and possible future embodiment of his invention." *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1344 (Fed. Cir. 2001). Thus, courts must avoid construing the claims to include elements described in the specification with respect to particular embodiments, but not required by the claims themselves. *Phillips*, 415 F.3d at 1320. Indeed, even if every embodiment described in the patent's specification contains a

particular element, that is not enough to justify importing the element into claims whose plain language does not expressly require it. *See id.*; *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) (collecting cases); *GE Lighting Sols., LLC v. AgiLight, Inc.*, 750 F.3d 1304, 1309-10 (Fed. Cir. 2014) ("[W]hile the specifications only disclose a single embodiment of an IDC connector in Figure 6, they do not disavow or disclaim the plain meaning of IDC connector or otherwise limit it to that embodiment.").

"[A] court 'should also consider the patent's prosecution history.'" *Phillips*, 415 F.3d at 1317 (quoting *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed Cir. 1995) (en banc)). "Yet because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes." *Id.*

Sometimes, a "court will need to look beyond the patent's intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period." *Teva Pharm.*, 574 U.S. at 331. In other cases, "claim construction . . . involves little more than the application of the widely accepted meaning of commonly understood words. . . . In such circumstances, general purpose dictionaries may be helpful." *Phillips*, 415 F.3d at 1314. However, such extrinsic evidence cannot be used to

"contradict claim meaning that is unambiguous in light of the intrinsic evidence." *Id.* at 1318-19, 1324.

## IV. Disputed Claim Terms

### A. '289 Patent, Claims 1, 3; '587 Patent, Claims 1, 3; 11-13; '156 Patent, Claim 12: "Actuation Member"

| Teva's Proposed Construction | Defendants' Proposed Construction |
|---|---|
| Plain and ordinary meaning in view of the claims, specification, and prosecution history.<br><br>"a component of the dose counter's actuator that transmits motion from the canister to the actuator" | "pin arranged to engage with a medicament canister and effect movement causing the dose counter to record a count" |

The parties' dispute is clear: Defendants contend that the actuation member recited in the claims of the '289 and '587 Patent is limited to a pin. It is not. Defendants' construction represents a classic and improper attempt to import limitations from preferred embodiments into the claims.

The parties do not dispute what an actuation member does—all agree that it transmits motion from the canister to the rest of the dose counter. If that motion is sufficient in magnitude, the dose counter will record a count. If that motion is insufficient in magnitude, the dose counter will not record a count. The parties are aligned in this understanding, as their proposed constructions reflect. The parties do disagree, however, about whether the recited actuation member must be a pin.

Defendants' proposed construction is incorrect. The plain meaning of an

"actuation member" is a "member" (i.e., component or part), of the "actuator,"[2] and is not limited to a pin. In the context of the Asserted Patents and Claims, it is clear the actuation member transmits motion from the canister and causes the actuator to move, just as Teva's construction explains.

The specification confirms this interpretation, disclosing that "an actuation member extend[s] through the communication aperture to transmit canister motion to the actuator." '289 Patent, 6:31-33; *id.* at 6:38-41 ("[T]he dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of a medicament canister.").[3]

Defendants cannot point to the requisite lexicography or disavowal in the specification that could justify narrowing the plain meaning of "actuation member" to require that it take the form of a "pin." *Supra* Section III; *Thorner*, 669 F.3d at 1365-66. Although even the consistent disclosure of a pin as the actuation member could not justify Defendants' limiting construction as a matter of law, *id.*; *Phillips*,

[2] Defendants do not dispute this plain meaning of "member," reflected in multiple dictionaries. *E.g.*, New Oxford American Dictionary 1091 (3rd ed. 2010) (defining "member" as "a constituent piece of a complex structure") (Ex. 7); Dictionary of Mechanical Engineering 246 (4th ed. 1996) ("considering the design of a mechanism or structure, a member is taken to be a single definable part, such as beam, plate or column, which can be easily analysed and stressed") (Ex. 8).

[3] For terms appearing in both the '289 and '587 Patents, citations to the common specification of the Asserted Patents refer to the '289 Patent. Identical disclosures appear in the '587 Patent.

415 F.3d at 1320, the vast majority of references to an "actuation member" in the specification do not suggest the concept of a pin. '289 Patent, 6:44-62 (referencing "actuation member" or "actuator member" five times without the word "pin").

Only once does the specification state that "[t]he dose counter may, apart from said at least a portion of the actuation member, be located in a counter chamber separate from the canister housing, the actuation member comprising a pin extending through an aperture in a wall which separates the counter chamber and the canister housing." *Id.* at 7:20-25. But this passage merely describes a single *embodiment* of the claimed invention—a form the claimed invention "may" take, and that is exemplary rather than restrictive. *Id.* at 7:20-25 ("the dose counter *may*" (emphasis added)); *Cadence Pharm. Inc. v. Exela PharmSci Inc.*, 780 F.3d 1364, 1369 (Fed. Cir. 2015). In other words, the specification's permissive statement that a disputed term "may" be one thing does not preclude it from being another. *Cadence*, 780 F.3d at 1369 ("The statement in the specification that the concentration of the buffer *'may be'* between 0.1 and 10 mg/ml is not limiting, because even if 'all of the embodiments discussed in the patent' included a specific limitation, it would not be 'proper to import from the patent's written description limitations that are not found in the claims themselves.'" (emphasis added)). Indeed, the Asserted Patents themselves make clear that "[v]arious modifications may be made to the embodiment shown without departing from the scope of the invention as defined by

the accompanying claims as interpreted under patent law." '289 Patent, 21:29-32. Here, longstanding precedent dictates that the specification's description of the actuation member *in a particular embodiment* as "comprising" a pin does not prohibit the actuation member from taking a different form in other embodiments. *Supra* Section III; *Jazz Pharm., Inc. v. Amneal Pharm., LLC*, 895 F.3d 1347, 1362 (Fed. Cir. 2018) ("We decline to read such limitations into the broad claim language based on the specification's use of the word 'contains' or 'includes' in the context of describing a certain embodiment.").

This is true even if the specification does not disclose other examples of what a term "may" be. *Supra* Section III. The Federal Circuit "has expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment." *Liebel-Flarsheim*, 358 F.3d at 906 (collecting cases); *GE Lighting*, 750 F.3d at 1309 ("[W]hile the specifications only disclose a single embodiment of an IDC connector in Figure 6, they do not disavow or disclaim the plain meaning of IDC connector or otherwise limit it to that embodiment."). Because the specification here does not "clearly express an intent to define" an actuation member as a pin (by providing an express definition), nor does it "make[] clear that the invention does not include" anything but a pin, the plain meaning of "actuation member" must prevail. *GE Lighting,* 750 F.3d at 1309 (quoting *SciMed Life*, 242 F.3d at 1341) (alteration in original).

For this reason, it is simply of no moment that embodiments of the dose counter illustrated by the figures depict an actuation member as a pin. The specification makes clear that the figures illustrate only embodiments of the invention, rather than defining the invention as a whole. '289 Patent, 11:11-13 ("FIG. 1 is an isometric view of a main body of *an embodiment of an inhaler related to the invention*") (emphasis added); *see also id.* at 11:6-10 ("[T]he present invention may be carried out in *various ways* and *preferred embodiment of a dose counter, inhaler* and methods of assembly, design and manufacture will now be described with reference to the accompanying drawings . . . ." (emphasis added)). Simply put, Teva "did not need to include a drawing" of a non-pin actuation member in order to claim one. *CCS Fitness, Inc. v. Brunswick Corp*., 288 F.3d 1359, 1367 (Fed. Cir. 2002). That is especially true where, as here, "[t]he drawings merely illustrated a particular embodiment of the claimed member and the specifications did not clearly assign a unique definition to '[actuation] member,' distinguish '[actuation] member' based on the prior art, disclaim subject matter or describe a [pin-shaped] '[actuation] member' as important to the invention." *Id.*; *Thorner*, 669 F. 3d at 1368; *Rexnord*, 274 F.3d at 1344 ("[A]n applicant is not required to describe in the specification every conceivable and possible future embodiment of his invention.").

Indeed, other aspects of the specification further refute Defendants' construction. Where the patentee wished to refer to an actuation member that is a

pin, the specification did so explicitly, by using the term "actuation pin." *See, e.g.*, '289 Patent, 12:22, 12:39, 12:54, 12:58, 13:16, 13:45, 15:49, 15:51 (all describing the preferred embodiment shown in the figures). The patentee used the narrower term "actuation pin" when describing figures depicting an embodiment with a pin-shaped actuation member, but used the broader term "actuation member" in elsewhere in the specification. '289 Patent, 6:31-62. The patentee clearly used two terms that had two different meanings, and selected the broader term for use in the claims. *Augme Techs., Inc. v. Yahoo! Inc.*, 755 F.3d 1326, 1333 (Fed. Cir. 2014) ("[D]ifferent claim terms are presumed to have different meanings." (quoting *Helmsderfer v. Bobrick Washroom Equip., Inc.*, 527 F.3d 1379, 1382 (Fed. Cir. 2008))). Defendants may not undo the patentee's selection by equating the broad term the patentee chose with the narrower one they prefer.

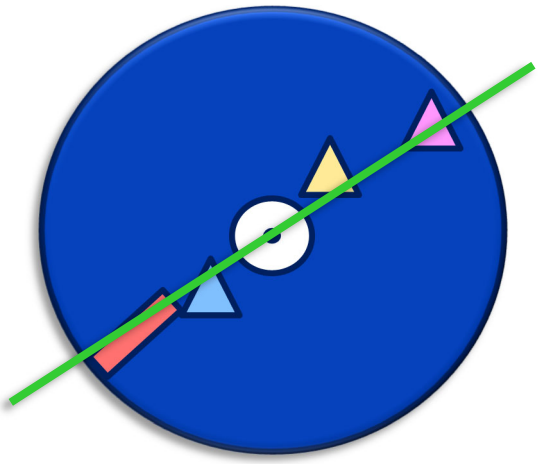
### B. '289 Patent, Claim 1; '587 Patents, Claims 1, 12, 21, 22: "[Lying or Lie] in a Common Plane Coincident with the Longitudinal Axis X" ("the Common Plane Limitation")

| Teva's Proposed Construction | Defendants' Proposed Construction |
|---|---|
| Plain and ordinary meaning in view of the claims, specification, and prosecution history.<br><br>Features lie on a common plane coincident with the longitudinal axis X if it is possible to draw a straight line connecting those features that passes through the center of the stem block. | "aligned in a single plane such that a straight line can be drawn though the center of the central outlet port, a canister support formation located directly adjacent to the actuation member, and the actuation member" |

The parties' competing constructions belie their essential agreement on what it means for three recited features of the inhaler to "lie in a common plane coincident with the longitudinal axis X." Teva and Defendants agree that three features lie on a common plane if a straight line can be drawn connecting all three of them. The parties further agree that the common plane is "coincident with the longitudinal axis X" if the line also passes through the center of the central outlet port (which is in the center of the valve stem block, illustrated below). The parties' sole disagreement is that Defendants improperly import an additional requirement: that a canister support formation cannot "lie in a common plane" with the other specified features unless that canister support formation also is "located directly adjacent to the actuation member." That additional limitation is utterly divorced from the language of the claims, finds no support in the specification, and directly contradicts the prosecution history, in which Teva *removed* such an "adjacency" requirement from its claims.

To illustrate the parties' dispute, consider the diagram below (a top-down view), where the blue circle represents the inhaler body, the "donut hole" in the middle represents the central outlet port with a black dot at its center, and the red rectangle represents an inner wall canister support formation. From this perspective, the "longitudinal axis X" extends straight out of the page from the black dot towards the reader. Under Teva's construction, an inhaler with an actuation member located at any of the blue, yellow, or pink triangles would satisfy the Common Plane

Limitation, because each triangle is intersected by a straight (green) line that also intersects the center of the central outlet port (black dot) and the canister support formation (red rectangle).



Under Defendants' construction, however, only the "blue triangle" configuration would infringe. Defendants argue that an inhaler with the "yellow triangle' or "pink triangle" configurations would fail to satisfy the Common Plane Limitation because, even though the actuation member and canister support formation *are in a common plane* with the center of the central outlet port (as the claims recite), the actuation member and canister support formation are not *also adjacent* (as the claim nowhere recites). Defendants' contention that components must be adjacent in order to lie in a common plain defies not only basic rules of geometry, but also the plain language of the claims, specification, and file history.

The plain language of claim 1 of the '289 and '587 Patents require that "the inner wall canister support formation, the actuation member, and the central outlet

port l[ie] in a common plane coincident with the longitudinal axis X." The limitation in question—and indeed, the rest of claim 1—is utterly silent as to any requirement that the canister support formation *also* be located directly adjacent to the actuation member.

Lest any doubt remain, the dependent claims extinguish it, by confirming that the patentee knew how to require adjacency of two claimed features. For example, claim 9 of each of the '289 and '587 Patents recite an inhaler "wherein the support rail merges with the inner wall *at a location adjacent the aperture*." No such language appears in any claim reciting the Common Plane Limitation. *Phillips,* 415 F.3d at 1314 ("Differences among claims can also be a useful guide in understanding the meaning of particular claim terms.").

The specification serves Defendants no better. It includes precisely two passages that discuss a canister support formation being adjacent to anything—both are plainly nonlimiting descriptions of embodiments. '289 Patent, 6:34-43, 15:33-35. The first is introduced as merely "a further aspect of the present invention." *Id.* at 6:34-43. The latter describes only what is "shown in FIGS. 7C and 7D," *id.* at 15:33-35, which, like all the figures, reflect a "*preferred embodiment* of a dose counter, inhaler and methods of assembly, design and manufacture," *id.* at 11:6-10. Neither statement comes close to the lexicography or disavowal required to redefine "coplanar with" to mean "coplanar with and adjacent to," as Defendants urge.

*Phillips,* 415 F.3d at 1316.

The prosecution history is the final nail in Defendants' claim construction coffin. When Teva amended its claims to add the Common Plane Limitation, it also *removed* a requirement that the recited canister support formation be "located directly adjacent the actuation member" (highlighting added):

1. (Currently Amended) An inhaler for metered dose inhalation, the inhaler comprising:

a main body having a canister housing,

a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister~~and movable relative thereto~~, and

a dose counter~~, the dose counter~~ having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,

wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall ~~and located directly adjacent the actuation member~~, and

wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port,

the inner wall canister support formation, the actuation member, and the central outlet port lying in a common plane coincident with the longitudinal axis X.

Ex. 9 (U.S. Patent App. No. 14/103,324, Mar. 7, 2016 Resp.), at 2 (highlighting added, strikeout showing language removed from claim, underlining showing newly-added language). The examiner allowed the claims in this revised form.

Thus, Defendants do not merely ask this Court to rewrite the claims, but to rewrite the claims in a manner the patentee explicitly rejected during prosecution. Both Federal Circuit precedent and common sense forbid such an approach. *Laryngeal Mask Co. v. Ambu*, 618 F.3d 1367, 1372-73 (Fed. Cir. 2010).

### C. ’289 Patent, Claim 7; ’587 Patent, Claims 7, 18: “Positioned at Opposite Ends of the Inside Surface of the Main Body to Face Each Other”

| Teva’s Proposed Construction | Defendants’ Proposed Construction |
|---|---|
| Plain and ordinary meaning in view of the claims, specification, and prosecution history.<br><br>“located on opposite sides from one another on the inside surface of the main body, and extending outwardly from the inner wall towards each other” | “positioned directly across from one another such that a straight line can be drawn from one support rail through the center of the longitudinal axis X to the facing support rail” |

The phrase “opposite ends” needs no construction. Nonetheless, the parties dispute this term because Defendants seek to imbue those two words with meaning that the evidence cannot possibly support. In Defendants’ view, “opposite ends” means “at either end of a line that passes through the center of the inhaler.” The claim language and specification cannot support such a narrow meaning for these simple terms. The Court should adopt Teva’s plain-meaning proposal.

Claim 7 of the ’289 and ’587 Patents require two support rails that “are positioned at opposite ends of the inside surface of the main body to face each other.” Defendants convert this simple language into a geometry problem, by requiring that the two support rails be “positioned directly across from one another such that a straight line can be drawn from one support rail through the center of the longitudinal axis X to the facing support rail.” In other words, Defendants require that the two support rails be diametrically opposed around the (somewhat) circular inhaler body.

The plain meaning of "opposite ends" is far broader.

For example, no one would dispute the statement that Los Angeles and Washington, D.C. are at "opposite ends" of the country, even though the line that connects them does not pass through the center of the U.S. 12:00 and 5:30 are at "opposite ends" of the clock but likewise are not positioned "such that a straight line can be drawn" from one to the other that passes "through the center" of the clock. And it is, of course, possible to waive to a friend at the "opposite end" of a round table even if you could be sitting even farther apart. These scenarios reflect the plain and ordinary meaning of the phrase "opposite ends," but would be excluded by Defendants' construction. Nothing in the claims, specification, or file history amounts to lexicography or disavowal that could justify such an approach.

To the contrary, when the specification describes the relationship of two objects on opposite ends of the same diameter (such that a line between them passes through the center), it does not describe them using the general phrase "opposite sides," but rather the far more precise language "diametrically opposed." For example, the specification describes the embodiment in Figure 7B as follows:

> As shown in FIG. 7B a diametrically opposed two-step support rail **146** is also provided and this diametrically opposed in the sense that a vertical plane (not shown) can pass substantially directly through the first rail **144**, the aperture **74**, a central aperture **148** of the valve stem block **40** (in which canister stem **25** is located) and the second two-step support rail **146**.

'289 Patent, 15:36-42. This detailed explanation provides a clear meaning for the term "diametrically opposed" that the specification uses consistently to convey this concept. *See, e.g.*, *id.* at 13:23-28 (describing "friction or control elements **128, 130**" located "at diametrically opposed positions" on a shaft in the embodiment of Figures 6A and 6D).

The *claims*, however, do not invoke this narrow language. Rather than require the canister support formations to be "diametrically opposed" from one another—language the patentee knew how to use when intended—claim 7 of the '289 and '587 Patents require only that the canister support formations be on "opposite ends" from one another. The patentee plainly did not intend to require more, having taken pains in the specification to use a distinct, narrower term to convey the meaning Defendants ascribe to "opposite ends." The patentee's choice to use "opposite ends" rather than "diametrically opposed" in the Asserted Claims must be credited, not lawlessly discarded to serve Defendants' interests in escaping infringement. *Augme Techs., Inc.*, 755 F.3d at 1333; *Phillips*, 415 F.3d at 1316 ("The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be . . . the correct construction.").

### D. '289 Patent, Claims 5, 8; '587 Patent, Claims 5, 8, 16, 19: "Steps Formed Thereon"

| Teva's Proposed Construction | Defendants' Proposed Construction |
|---|---|
| Plain and ordinary meaning in view of the claims, specification, and prosecution history.<br><br>"a location of changing width dimension thereon" | "A stepwise increase in the extent to which the support rail extends inwardly" |

Again, Defendants seek construction of a term that has a plain meaning. On its face, Defendants' construction does not add any clarity to the claim language itself. However, the conferral process revealed that by virtue of their construction, Defendants hope to exclude very specific embodiments from the scope of the Asserted Claims.[4] Setting aside the fact that Defendants' construction does not accomplish this goal, there is no basis to exclude those embodiments.

Plaintiffs and Defendants part ways with respect to what constitutes a "step." While their construction does not make their position plain, Defendants stated during the parties' meet and confer discussions that their construction is intended to prohibit the end of a support rail or a gradual change in a support rail's inwardly-extending width from constituting a "step." There is no basis for such *ad*

[4] Defendants argue alternatively that the claims should be *limited* to preferred embodiments (e.g., "actuation member") or should be read to *exclude* preferred embodiments (e.g., "step(s) formed thereon"). This inconsistent approach belies the litigation-driven nature of Defendants' constructions, which are wholly divorced from the terms' plain meaning as reflected in the specification.

*hoc* efforts. Contrary to Defendants' position, the specification provides a broad description of support rails with steps:

> Each said [support] rail may be stepped, in that it may have a first portion located towards a medicine outlet end or stem block of the canister housing which extends inwardly a first distance from a main surface of the inner wall and a second portion located toward an opposite end of the canister chamber which extends inwardly a second, smaller distance from the main surface of the inner wall.[5]

'289 Patent, 7:1-7. Consistent with this description, one example of a "stepped" support rail is shown in Figures 7A-7D, in which a rail contains a "second step **164** at which the rail merges into the main inner wall **50** main surface." *Id.* at 16:2-3. As the "preferred embodiment" of Figure 7C plainly shows, *id.* at 11:5-10, step 164 is both the end of a support rail, and reflects a gradual change in support rail width.

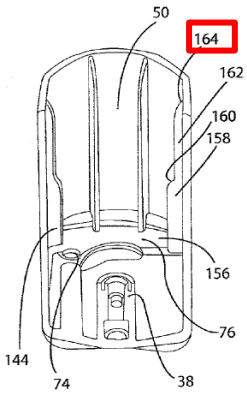



FIG. 7C

[5] Teva does not perceive a substantive difference (and Defendants have not identified one) between its language of "width dimension" and Defendants' language of "extent to which the support rail extends inwardly." The specification refers to the "inwardly-extending width" of a support rail. *Id.* at 15:62-16:3.

As evidenced by the preferred embodiment, neither of these characteristics preclude a location on a support rail from being a "step." Adoption of Defendants' construction would do violence to the specification by concluding that that what it describes as "step **164**" is not, in fact, a step. "A claim construction that excludes the preferred embodiment is rarely, if ever, correct and would require highly persuasive evidentiary support." *Adams Respiratory Therapeutics, Inc. v. Perrigo*, Inc., 616 F. 3d 1283, 1290 (Fed. Cir. 2010).

### E. '289 Patent, Claim 3; '587 Patent, Claims 3, 13, 20-22; '512 Patent, Claims 1, 6: "Aperture"[6]

| Teva's Proposed Construction | Defendants' Proposed Construction |
|---|---|
| Plain and ordinary meaning in view of the claims, specification, and prosecution history.<br><br>"an opening or open space: hole" | "hole" |

Teva's construction reflects the plain and ordinary meaning of the term aperture, consistent with the term's use throughout the specification. Defendants' construction, by contrast, reflects a truncated version of the plain and ordinary meaning of the word "aperture," and is flatly inconsistent with the term's broader use in the specification. Defendants' position, which limits an aperture to a "hole," to the exclusion of an "opening" or "open space," is plainly incorrect.

[6] Although reflected in the parties' citations to evidence, claim 1 of the '512 Patent appears to have been inadvertently omitted from the first column of the Joint Claim Construction Chart. Dkt. No. 102, at 9-10.

The Asserted Patents use the term "aperture" to describe two different aspects of the inventions claimed. In the '289 and '587 Patents, certain claims refer to an aperture through which the actuation member extends, such that the actuation member extends out of the counter chamber and can make contact with the medicament canister. *See, e.g.*, '289 Patent, claim 3; '587 Patent, claims 3, 13. In the '512 Patent, by contrast, the claims recite apertures that receive pins, wherein the pins and apertures are heat staked together. *See, e.g.*, '512 Patent, claims 1, 6. Teva's construction applies to both these aspects of the asserted claims by adopting the plain and ordinary meaning of the term "aperture" straight out of Merriam Webster's Collegiate Dictionary: "an opening or open space: hole." Ex. 10 at 57.

Read with an eye towards understanding the claims rather than manufacturing a dispute, it is clear that an "aperture" need not be limited to a hole. For example, the apertures that receive pins as part of a heat staking process are better described as cavities rather than holes, in that they are structures *into* which the pins are inserted. The Court should embrace the plain and ordinary meaning of aperture that satisfies all manners in which the claim term is used.

Defendants' unnecessary and limited construction must be rejected. Despite extensive conferral, Teva still does not understand what, if any, purpose is served by Defendant's endorsement of the term "hole"—part of the ordinary meaning—but rejection of the "opening or open space" language that supplies the rest of the

meaning. When pressed, Defendants cited concerns that "an open space" could be anything, such as "an open field." Plainly, the remaining language of the relevant claims—which are directed to inhalers rather than the great outdoors—forecloses Defendants' concerns. In the '289 and '587 Patents, the actuation member of the dose counter must extend through the "aperture" to make contact with the medicament canister, all of which is located in the context of an inhaler body. Furthermore, in the '512 Patent, the "apertures" are located either on an inhaler body or a dose counter chassis, such that they can receive pins for heat staking. Claim terms must be construed in the context of the claims in which they occur, not in a vacuum. *Phillips*, 415 F.3d at 1314 ("[T]he context in which a term is used in the asserted claim can be highly instructive."). When viewed through the appropriate lens of the claim as a whole, the Asserted Claims cannot read on "an open field"; by their plain language, however, their recited "apertures" permit "open space" between or among inhaler parts within the inhaler or dose counter body.

### F. '156 Patent, Claims 1, 9: "Count Pawl"

| Teva's Proposed Construction | Defendants' Proposed Construction |
|---|---|
| Plain and ordinary meaning in view of the claims, specification, and prosecution history.<br><br>"a pawl that is a component of the dose counter that is capable of engaging with a second tooth of the rachet wheel" | "a pawl that is part of the dose counter, separate from an actuator pawl, that is arranged to engage with a second tooth different from the first tooth of the ratchet wheel" |

Claim 1 of the '156 Patent recites "a count pawl that is arranged to engage with a second tooth of the ratchet wheel." The parties' dispute focuses on whether, as Defendants propose, the "count pawl" must be "separate from the actuator pawl." Once again, Defendants' proposal is unsupported, and the Court should reject it in favor of Teva's plain-meaning approach.

By their own terms, the claims require only that the dose counter comprise a "count pawl arranged to engage with a second tooth of the ratchet wheel." They do not require the "count pawl" to be "separate" from the "actuator pawl." '156 Patent, Claims 1, 9.

Defendants' contrary construction violates established precedent that "the use of two terms in a claim requires that they connote different meanings, not that they necessarily refer to two different structures." *Applied Med. Resources Corp. v. U.S. Surgical Corp.*, 448 F.3d 1324, 1333 n.3 (Fed. Cir. 2006). Thus, the fact that claims use different words to refer to the "count pawl" and "actuator pawl," does not necessitate that they are physically separate components. *See, e.g.*, *Retractable Techs., Inc. v. Becton, Dickinson & Co.*, 653 F.3d 1296, 1303-04 (Fed. Cir. 2011) (rejecting construction requiring "retainer member" and "needle holder" to "be two separate parts" merely because "the asserted claims list the 'retainer member' and 'needle holder' as separate claim limitations"); *In re Papst Licensing Digi. Camera Pat. Litig.*, 778 F.3d 1255, 1262-65 (Fed. Cir. 2015) (rejecting construction requiring

"interface device" and "second connecting device" to require physical separateness); *Cochlear Ltd. v. Oticon Med. AB*, No. 18-6684-BRM-DEA, 2019 WL 3943014, at *6 (D.N.J. Aug. 21, 2019) (rejecting construction requiring "screw thread," "flange," and "circumferential groove" to refer to separate structures).

Nothing here justifies departure from this established precedent. In their identification of supporting evidence, Defendants relied on various descriptions and figures in the specification, showing separate structures for these claim terms, to support their proposed construction. Ex. 11 (Defs.' Preliminary Claim Constructions and Supporting Evidence (May 5, 2021)), at 12 (citing 13:40-15:32; 14:60-15:3; Figs. 6D, 6G; Figs. 10A-10F). However, as with the terms discussed above, the '156 Patent makes clear that those descriptions and figures are exemplary only. *See* '156 Patent, 11:6-10 ("The present invention may be carried out in various ways and ***preferred embodiment*** of a dose counter, inhaler and methods of assembly, design and manufacture will now be described with reference to the accompanying drawings . . . ." (emphasis added)); *id.*, 21:29-32 ("Various modifications may be made to the embodiment shown without departing from the scope of the invention as defined by the accompanying claims as interpreted under patent law."). Defendants' proposal should thus be rejected.

### G. '156 Patent, Claim 1: "First Reset Position"/ '156 Patent, Claims 1-2: "Canister Fire Configuration"/ '156 Patent, Claims 1-2: "Count Configuration"

| Teva's Proposed Constructions | Defendants' Proposed Constructions |
|---|---|
| "first reset position"<br><br>Plain and ordinary meaning in view of the claims, specification, and prosecution history.<br><br>"a position of the actuator in which the actuator pawl is brought into engagement with the first tooth of the ratchet wheel and which is before the canister fire configuration" | "first reset position"<br><br>"configuration in which the actuator pawl is above the datum plane, but closer to the datum plane than in the start configuration, and is just engaged with one of a tooth of the ratchet wheel" |
| "canister fire configuration"<br><br>Plain and ordinary meaning in view of the claims, specification, and prosecution history.<br><br>"a configuration of the dose counter in which the medicament canister fires medicament" | "canister fire configuration"<br><br>"configuration in which the actuator pawl is lower than in the first reset position and below the datum plane and the medicament is ejected" |
| "count configuration"<br><br>Plain and ordinary meaning in view of the claims, specification, and prosecution history.<br><br>"a configuration of the dose counter whereby the dosage indicator has indicated a count" | "count configuration"<br><br>"configuration in which the actuator pawl is further below the datum plane than when in the canister fire position and the dose counter has counted one dose" |

The parties' competing constructions of "first reset position," "canister fire configuration," and "count configuration" reflect the same fundamental

disagreement. Plaintiffs propose that the terms should be given their plain and ordinary meanings, as apparent from the context of claim 1. Defendants, by contrast, contend that the claims should be construed to include limitations beyond those explicit in the claim, including that they be construed to require the actuator pawl to be in particular locations at or between each configuration. But the Asserted Patents do not use the disputed terms in the manner Defendants suggest, and Defendants' efforts to import extraneous limitations should be rejected.

Here, the language of claim 1 clearly indicates each term's meaning:

> **1.** A dose counter for a metered dose inhaler . . .
>
> wherein the actuator is arranged to define ***a first reset position in which the actuator pawl is brought into engagement with the first tooth***,
>
> wherein the actuator is further arranged such that, during ***a canister fire sequence, when the actuator is in a second position, which is after the first reset position and at a canister fire configuration, the medicament canister fires medicament before the dose counter reaches a count configuration***, and when the actuator is in ***a third position after the second position, the count pawl resiliently jumps over the second tooth and the dose counter reaches the count configuration, whereby the dosage indicator has indicated a count***,
>
> wherein, in the canister fire configuration, the actuator pawl is below a datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister.

As the above language makes plain, the first reset position requires that the "actuator pawl is brought into engagement with the first tooth [of the ratchet wheel]." It must

occur before the canister fire configuration, "which is after the first reset position." The "count configuration" occurs when the "dosage indicator has indicated a count," and the "canister fire configuration" occurs when "the medicament canister fires medicament." Because claim 1 makes each of these requirements explicit, no additional construction is necessary.

Defendants' proposed constructions improperly import additional limitations that are wholly absent from claim 1, including the following:

- "First reset position": actuator pawl is "above the datum plane, but closer to the datum plane than in the start configuration;"
- "Canister fire configuration": actuator pawl is "lower than in the first reset position;"
- "Count configuration": actuator pawl is "further below the datum plane than when in the canister fire position."

Nothing in the plain and ordinary meaning of claim 1's language imposes these requirements—and indeed, claim 1 makes no reference to a "start" configuration whatsoever (a phrase Defendants have conjured unnecessarily). To the contrary, where the claims do limit the location of the "actuator pawl," they do so explicitly. For example, claim 1 requires that "in the canister fire configuration, the actuator pawl is below a datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister." (It does not require, as Defendants

propose, that in this canister fire configuration, the actuator pawl is "lower than in the first reset position.") Dependent claims 6 and 8 also impose additional limitations that specify the location of the actuator in various positions and/or configurations by specifying absolute distances (e.g., "1.5 to 2.0 mm"). That the claims expressly specify the location of the actuator in some claims, but not the ones that Defendants suggest, demonstrates that Defendants' proposed construction is improper. *Phillips*, 415 F.3d at 1324-25 (refusing to construe independent claim to require limitation where similar limitations were recited in various dependent and independent claims); *Env't Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 699 (Fed. Cir. 1983) ("It is improper for courts to read into an independent claim a limitation explicitly set forth in another claim.").

To justify adding extraneous limitations, Defendants would need to prove that the specification of the Asserted Patents explicitly defined the claim terms to include those limitations or clearly disavowed claim scope beyond those limitations. *Supra* Section III; *Toshiba*, 681 F.3d at 1369; *Thorner*, 669 F.3d at 1365-66. Defendants can prove neither. Defendants have not identified any definition of these terms in the specification or prosecution history, much less one that imposes the additional limitations that they seek to add regarding location of the actuator pawl. To the contrary, the specification refutes Defendants' position. The "Abstract" and "Summary of the Invention" do not use the terms "above," "further below," or

"lower" when describing the positions of the actuator. Instead, and consistent with the claim language (and contrary to Defendants' proposed constructions), the specification discloses that the "canister fire" and "count" configurations are "determined by a position of the actuator relative to a datum" and not relative to each other. '156 Patent, Abstract, 4:46-65.

In their identification of supporting evidence, Defendants suggested that Figure 10 shows the relationship embodied by their proposed constructions. *See* Ex. 11, at 13-15 (citing '156 Patent, 13:40-15:32; Figs. 10A-10F). As the patents make clear, however, Figure 10 describes only "preferred embodiments," rather than the full scope of the claimed inventions, and provides explicitly that "[v]arious modifications may be made to the embodiment shown without departing from the scope of the invention as defined by the accompanying claims." '156 Patent, 21:29-31; *id.*, 11:6-10 ("The present invention may be carried out in various ways and ***preferred embodiment*** of a dose counter, inhaler and methods of assembly, design and manufacture will now be described with reference to the accompanying drawings . . . ." (emphasis added)). In clear violation of controlling precedent, Defendants ignore the specification's disclosure and attempt to limit the claims on the basis of one embodiment. *Phillips*, 415 F.3d at 1320; *Kara Tech. Inc. v. Stamps.com Inc.*, 582 F.3d 1341, 1348 (Fed. Cir. 2009) ("The patentee is entitled to the full scope of his claims, and we will not limit him to his preferred embodiment

or import a limitation from the specification into the claims.").

### H. '156 Patent, Claim 1: "Canister Fire Sequence"

| Teva's Proposed Construction | Defendants' Proposed Construction |
|---|---|
| Plain and ordinary meaning in view of the claims, specification, and prosecution history.<br><br>"a sequence of configurations and positions that occur before, while, and after the medicament canister fires medicament" | "process of ejecting medicament from an inhaler where the actuator pawl follows a particular sequence of movement from the start configuration to the reset configuration, to the fire configuration, to the count configuration, before returning to the start configuration upon release of pressure on the canister, where in the start configuration, prior to depression of the canister, the count pawl is engaged with a tooth of the ratchet wheel and the actuator pawl is spaced from the ratchet wheel." |

Teva's straightforward construction of "canister fire sequence" makes explicit the term's plain and ordinary meaning. Although it is not clear what Defendants' proposal seeks to accomplish, it violates multiple principles of claim construction, including by importing additional limitations into the claims.

First, Defendants' proposed construction incorporates multiple limitations relating to the "start configuration." But the term "start configuration" does not appear in claim 1 at all. Instead, the term appears only in claims 5-6, 8, and 10, which depend from claim 1. Because claim 1 itself does not contain any limitations regarding the "start configuration," it is therefore improper to construe claim 1 to include such limitations. *See, e.g.*, *Phillips*, 415 F.3d at 1324-25; *Env't Designs*, 713

F.2d at 699.

Second, Defendants' proposed construction requires that "in the start configuration, prior to depression of the canister, the count pawl is engaged with a tooth of the ratchet wheel." That limitation has no basis in claim 1, which describes the location of the "actuator pawl," not the "count pawl." Even claim 10, the only claim that mentions the location of the "count pawl," does not state that the count pawl is engaged with a tooth of the ratchet wheel.

Third, Defendants' proposed construction requires that the "actuator pawl" return "to the start configuration upon release of pressure on the canister, where . . . the actuator pawl is spaced from the ratchet wheel." Whatever that means, neither claim 1 nor the specification contains any such requirement.

In their identification of supporting evidence, Defendants cited the same portions of the specification and prosecution history that they relied upon for the position/configuration terms. Ex. 11, at 14. As explained above, the specification is explicit that those disclosures refer only to particular "embodiments" of the invention and cannot limit the claims. '156 Patent, 11:6-10, 21:29-32. By contrast, the "Summary of the Invention" describes the "fire canister fire sequence" using language similar to the claims. *See, e.g.*, '156 Patent, 4:55-65 ("[T]he actuator and incremental output member being configured to have predetermined canister fire and count configurations in a canister fire sequence . . . wherein the actuator is arranged

to reach a position thereof in the count configuration at or after a position thereof in the canister fire configuration."). And the cited portions of the prosecution history do not refer to the "canister fire sequence" at all. Such "evidence" does not meet the "exacting" standards for lexicography or disavowal needed to limit the claims' plain and ordinary meaning. *Thorner*, 669 F.3d at 1366. Defendants' effort to read in extraneous limitations is, again, contrary to controlling precedent and should be rejected. *Phillips*, 415 F.3d at 1320; *Kara Tech.*, 582 F. 3d at 1348.

## I. '156 Patent, Claim 1: "Datum Plane Which Passes Through a Shoulder of a Valve Stem Block Configured to Receive the Medicament Canister"

| Teva's Proposed Construction | Defendants' Proposed Construction |
|---|---|
| Plain and ordinary meaning in view of the claims, specification, and prosecution history.<br><br>"a plane that passes through a shoulder of the portion of the inhaler body that engages the valve stem and is perpendicular to the direction of movement of the medicament canister" | "plane or line passing through the bottom surface of a structure into which the valve stem of a medicament canister is inserted, wherein the bottom surface is where the valve stem block meets a passageway to a nozzle for directing the canister contents towards an air outlet" |

Claim 1 of the '156 Patent states that "in the canister fire configuration, the actuator pawl is below a ***datum plane*** which passes through a shoulder of a valve stem block configured to receive the medicament canister." Apart from that statement, claim 1 does not contain any other references to the datum plane or the "shoulder" of the "valve stem block" through which the "datum plane" passes. Given that the language surrounding "datum plane" in claim 1 clearly defines the

term, Teva does not believe any construction of the term is necessary. But to the extent the Court concludes construction would be helpful, it should adopt Teva's proposal, which reflects the plain language of claim 1—i.e., that a datum plane must pass through a shoulder of the valve stem block (where the valve stem block is the portion of the inhaler body that engages the valve stem). Defendants' proposal, by contrast, imports extraneous limitations that run contrary to bedrock principles of claim construction.

Defendants do not appear to dispute that the term "datum" carries its plain and ordinary meaning, which, as explained by one technical dictionary cited by both sides, is "a line from which all measurements are made." Dictionary of Mechanical Engineering 101 (4th ed. 1996) (Ex. 12). Instead, Defendants seek to redefine the related but distinct term "shoulder." In particular, Defendants seek to rewrite the claim such that the "datum plane" need not pass through "a shoulder" of the valve stem block,[7] as the claims provide clearly and explicitly, but instead must pass through the "bottom surface" of the valve stem block, which according to Defendants, is the location "where the valve stem block meets a passageway to a nozzle for directing the canister contents towards an air outlet." Defendants'

[7] The parties agree that the valve stem block is "a structure into which the valve stem of a medicament canister is inserted" or "a portion of the inhaler body that engages a valve stem." Dkt. No. 102, at 8. Neither side has suggested that the differences in language are material.

cumbersome and baseless effort to redraft the claim should be rejected.

Contrary to Defendants' proposal, nothing in the intrinsic record suggests that the term "shoulder" should be construed to mean something other than its plain and ordinary meaning—i.e., any portion of the "valve stem block" that resembles a shoulder. Indeed, the claim language makes clear that Defendants' construction, which seeks to limit the meaning of "shoulder" to one specific location in the "valve stem block" (i.e., the bottom surface) is incorrect. Specifically, claim 1 references "***a*** shoulder", not "***the*** shoulder." Under Federal Circuit law, "an indefinite article 'a' or 'an' in patent parlance carries the meaning of 'one or more'" and this principle "is best described as a rule, rather than merely as a presumption or even a convention." *Baldwin Graphic Sys., Inc. v. Siebert, Inc.*, 512 F.3d 1338, 1342 (Fed. Cir. 2008) (quoting *KCJ Corp. v. Kinetic Concepts, Inc.*, 223 F.3d 1351, 1356 (Fed. Cir. 2000)). By referring to "a shoulder," claim 1 therefore plainly permits the "valve stem block" to have more than one shoulder—flatly inconsistent with Defendants' proposed construction limiting the claimed "shoulder" to the "bottom surface" of the valve stem block.

Other claim language confirms Teva's proposed construction. Unlike claim 1, which refers only to a "datum plane which passes through a shoulder of the valve stem block," claim 13, which depends from claim 1, expressly requires the "shoulder" to be "a bottom surface within the value stem block." Had the patentee

intended for the "shoulder" to always refer to a "bottom surface," as Defendants propose, this additional limitation in claim 13 would be surplusage. As written, however, claim 13 makes clear that the term "shoulder," on its own, is not limited to "a bottom surface within the valve stem block." *See, e.g.*, *Phillips*, 415 F.3d at 1324-25; *Env't Designs*, 713 F.2d at 699.

The only extrinsic evidence of record also contradicts Defendants' position. Consistent with Teva's proposed construction, numerous dictionaries confirm that the plain and ordinary meaning of "shoulder" refers to any "shoulder-like" structure, not solely the bottom surface of an object. *See, e.g.*, New Oxford American Dictionary 1617 (3rd ed. 2010) ("a part of something resembling a shoulder in shape, position, or function") (Ex. 13); Random House Webster's College Dictionary 1197 (1998) ("a shoulderlike part or projection"; "a steplike change in the contour of an object") (Ex. 14); Webster's Third New International Dictionary of the English Language Unabridged 2104 (2002) ("a part suggesting a human shoulder in shape, position, or function") (Ex. 15); Webster's New World College Dictionary 1327 (4th ed. 1999) ("something like a shoulder in shape or position; shoulderlike projection") (Ex. 16).

Similarly, other patents describing metered dose inhalers use the term "shoulder" to refer to shoulder-like structures and not the bottom surface. For example, U.S. Patent No. 6,640,805 ("Castro") (Ex. 17) describes a "valve stem **24"**

which "may include an angled shoulder **24*c***":

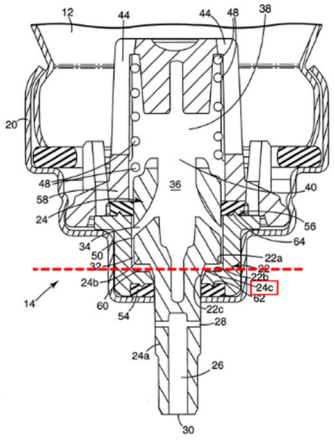


Fig. 3

Ex. 17, 5:53-61, Fig. 3 (markup added). As Figure 3 illustrates, "shoulder 24*c*" is a shoulder-like structure that is ***not*** a "bottom surface," "where the valve stem block meets a passageway to a nozzle for directing the canister contents towards an air outlet," as Defendants' proposal requires. Defendants' construction thus violates both the intrinsic and extrinsic evidence of record.

In their identification of supporting evidence, Defendants again rely on portions of the specification, Ex. 11, at 16 (citing '156 Patent, 13:40-15:32; Figs. 10A-10F); expressly described in the specification as referring to particular "embodiments," which the specification clarifies may have "various modifications" made to them "without departing from the scope of the invention as defined by the accompanying claims." '156 Patent, 11:6-10; *id.* at 21:29-32. Defendants also cite portions of the prosecution history. Ex. 11, at 16 (citing Office Action Resp. at 5-8 (Aug. 22, 2017); Office Action Resp. at 5-9 (Apr. 20, 2107); Office Action Resp. at

5-9 (Sept. 9, 2016)). But none of the cited statements define the datum plane to be the "bottom surface" of the "valve stem block," much less do so (as required to define the claim term) clearly and unmistakably. *Thorner*, 669 F.3d at 1365-66. They therefore cannot overcome the plain and ordinary meaning of the term "shoulder."

### J. '156 Patent, Claim 12: "Separate Counter Chamber"/ '512 Patent, Claims 2, 3: "Dose Counter Chamber"

| Teva's Proposed Construction | Defendants' Proposed Construction |
|---|---|
| "separate counter chamber"<br><br>Plain and ordinary meaning in view of the claims, specification, and prosecution history.<br><br>"a separate chamber of the inhaler in which the dose counter is located" | "discrete space or cavity defined by the main surface of the inner walls and the inner wall through which a portion of the actuation member extends in which the dose counter is located" |
| "dose counter chamber"<br><br>Plain and ordinary meaning in view of the claims, specification, and prosecution history.<br><br>"a chamber of the inhaler in which the dose counter is located" | "space or cavity defined by the main surface of the inner walls and the inner wall through which a portion of the actuation member extends in which the dose counter is located" |

Teva understands the parties' dispute to be limited to a simple issue: whether the recitation of a "counter chamber" in claims 2 and 3 of the '512 Patent and claim 12 of the '156 Patent require that the claimed system include such a chamber, or whether it requires that the chamber be created by two particular walls of the inhaler body. The clear answer is the former—the relevant claims of the

'512 and '156 Patents do *not* impose any requirements as to how the counter chamber is formed. Defendants' constructions represent yet another effort to import extraneous limitations that the law does not allow courts to introduce.

Nothing in the claim language supports Defendants' novel limitations. Claim 2 of the '512 Patent, for example, merely sets out the spatial relationship between the dose counter chamber, medicament canister, and body of the inhaler by providing that the dose counter chamber is located within the inhaler body at "a location beneath the medicament canister." Claim 12 of the '156 Patent is similar, and provides that the body of the inhaler "includes a canister-receiving portion and a separate counter chamber." To be sure, the latter claim also states that the body of the inhaler has "wall surfaces separating the canister-receiving portion and the counter chamber." But it does require, or even suggest, that the counter chamber is formed exclusively by these "wall surfaces." The claim language requires only what Teva's construction does—that the counter chamber be located in the inhaler body, and be separate from the medicament receiving portion.

The '512 and '156 Patents' specifications also undermine Defendants' proposals. The '512 Patent's specification uses the term "dose counter chamber" sixteen times. Crucially, not one of those uses states that the walls and inner walls of the body of the inhaler define the dose counter chamber. *See, e.g.*, '512 Patent, 4:39-50 (setting out a preferred embodiment and describing components within

dose counter chamber); *id.* at 8:35-40, 8:44-50, 12:43-55 (all similar). The same is true of the specification's single use of the term "separate counter chamber." *See* '156 Patent, 6:24-33. And Defendants can point to no evidence the prosecution history that suggests, let alone mandates, a contrary meaning. Absent any reason to justify a departure from the plain meaning of the disputed terms, *see GE Lighting*, 750 F.3d at 1309, Defendant's constructions must be rejected.

### K. '156 Patent, Claim 12: "The Body"

| Teva's Proposed Construction | Defendants' Proposed Construction |
|---|---|
| Plain and ordinary meaning in view of the claims, specification, and prosecution history.<br><br>"inhaler body" - '156 Patent, 22:64, 67<br><br>"dose counter body" - '156 Patent, 22:66 | This term is indefinite. |

Defendants argue that the term "body" as used in claim 12 of the '156 Patent is indefinite, even though the claim clearly uses the term first to refer to the body of the inhaler, and then to refer to the body of the dose counter. Defendants stretch the law of indefiniteness too far.

Under 35 U.S.C. § 112 ¶ 2, a patent "specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." To prove that a patent fails to meet this requirement, and therefore that a claim is invalid for indefiniteness, a defendant

must establish by clear-and-convincing evidence that the claims "read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). The standard recognizes that "absolute precision is unattainable" and that some modicum of uncertainty is the "price of ensuring the appropriate incentives for innovation." *Id.* at 909-10 (quoting *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 731 (2002)).

As an initial matter, Defendants' indefiniteness argument is premature. As courts in this and other districts have recognized, indefiniteness arguments are best reserved for trial, because of the "high burden of proof on a party challenging the patent based on indefiniteness," the dispositive nature of the ruling, and the lack of expert testimony at claim construction. *E.g.*, *Adapt Pharma Operations Ltd. v. Teva Pharm. USA, Inc.*, No. 16-7721-JLL, 2019 WL 1789463, at *4 (D.N.J. Apr. 24, 2019); *Int'l Dev. LLC v. Richmond*, No. 9-2495-GEB, 2010 WL 4703779, at *6 (D.N.J. Nov. 12, 2010).

Even were the Court to consider Defendants' indefiniteness argument now, Defendants fail to prove that the term "body" is indefinite as it is used in claim 12. Claim construction is ultimately a matter of "context." *Phillips*, 415 F.3d at 1313. Thus, "the same claim term can have different meanings depending on the context

of how the term is used within the claims and the specification." *Aventis Pharm. Inc. v. Amino Chems. Ltd.*, 715 F.3d 1363, 1374 (Fed. Cir. 2013). And a uniform construction is "particularly" inappropriate "where it would lead to a 'nonsensical reading.'" *Id.* (quoting *Microprocessor Enhancement Corp. v. Tex. Instruments Inc.*, 520 F.3d 1367, 1375 (Fed. Cir. 2008)).

Here, the POSA would understand from the language of claim 12 that the term "body" refers to two different components of the invention:

> **12.** An inhaler as claimed in claim **11** in which ***[1] the body*** includes a canister-receiving portion and a separate counter chamber; ***[2] the body***, ratchet wheel and actuator being located inside the counter chamber, ***[3] the body*** of the inhaler having wall surfaces separating the canister-receiving portion and the counter chamber, the wall surfaces being provided with a communication aperture, an actuation member extending through the communication aperture to transmit canister motion to the actuator.

In the first and third instances of the term "body," the POSA would understand the term to refer to the "inhaler body"; and in the second, the POSA would understand that the term to refer the "dose counter body." The specification confirms the straightforward meaning of the claim language. For example, as to the dose counter body ([2]), the specification states that the "dose counter" comprises "an incremental counting system for counting doses," which has "a main body," an "actuator," and an "incremental output member," which the patent elsewhere describes as a "ratchet wheel"—the same components associated with the [2] body in claim 12. '156 Patent, 4:46-65, 5:22-25. As to the inhaler body ([1], [3]), the

specification states the "inhaler main body may include a canister receiving portion and a separate counter chamber, the dose counter being located within the main body thereof, the incremental output member and actuator thereof inside the counter chamber." '156 Patent, 60:20-33. Thus, the POSA would understand that the term "body" referred to either the "dose counter body" or the "inhaler body," depending on usage. Guided, at a minimum, by those statements, the POSA would understand the meaning of the term "body" as it is used in claim 12 with reasonable certainty.

Rather than make a meaningful attempt to understand the term "body" based on the intrinsic record, Defendants' indefiniteness argument seeks to manufacture the illusion of ambiguity where none exists. Significantly, of the two defendant groups, only Cipla professed any difficulty in understanding the meaning of claim 12 in its invalidity contentions. Aurobindo was able to understand the claim—a proposition inconsistent with a finding of indefiniteness. *See, e.g., Sonix Tech. Co. v. Publ'ns Int'l, Ltd.*, 844 F.3d 1370, 1378-79 (Fed. Cir. 2017) (claim term not indefinite, in part, because defendant's expert had "no difficulty in applying" it).

For its part, Cipla argued that the term "body" in claim 12 is indefinite for two reasons: (1) the "body" in claim 12 could not refer to the "inhaler body," as in claim 1, because that would render claim 12 "structurally impossible" because the "'body' cannot both contain the separate counter chamber and be located inside the counter chamber" and (2) the "body" in claim 12 could not refer to anything other than the

inhaler body else because the term would then lack an antecedent basis (in other words, because "body" is preceded by the definite article "the," it must refer back to a prior usage of the term carrying an indefinite article, such as "an" or "a"). Cipla Invalidity Contentions 337 (Ex. 18). Neither argument is correct.

With respect to (1), Cipla fails to address the relevant issue. The relevant question is not whether claim 12 makes sense to Cipla's lawyers, but rather, whether the POSA, who would understand how inhalers and dose counters function, would understand its meaning with reasonable certainty. *Nautilus*, 572 U.S. at 901; *BASF Corp. v. Johnson Matthey Inc.*, 875 F.3d 1360, 1365-68 (Fed. Cir. 2017). To that question, Cipla offers no evidence at all, which forecloses its challenge here. *See, e.g.*, *BASF Corp.*, 875 F.3d at 1365-68 (reversing judgment of indefiniteness where record did not support finding that POSA would have failed to understand the claims with reasonable certainty).

Moreover, Cipla's logic is backwards. Before concluding that a term has a uniform meaning, a court must consider whether providing it such a reading would render the claim nonsensical. *Aventis Pharm.*, 715 F.3d at 1374; *Microprocessor Enhancement*, 520 F.3d at 1375. Thus, in this case, the concern that construing the term "body" to refer to the "inhaler body" all three times it is used in the claim would result in a structural impossibility is a reason to acknowledge that the term "body" has multiple meanings in the claim, not a basis for holding the claim indefinite. To

the extent that the POSA would understand the recitation of "body" in the claim to refer to the inhaler body initially and then the dose counter body—and based on the disclosure of the specification and the context of the claim, that would be abundantly clear—the premise of Cipla's argument is wrong, and the claim cannot be indefinite.

With respect to (2), Cipla misstates the law. Under a long line of precedent, a claim is not invalid for lack of antecedent basis if, as in this case, the POSA would have understood its meaning based on context. *See, e.g.*, *Energizer Holdings, Inc. v. ITC*, 435 F.3d 1366, 1370-71 (Fed. Cir. 2006); *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1319 (Fed. Cir. 2005); *Intell. Ventures I, LLC v. Ricoh Am. Corp.*, No. 13-474-SLR-SRF, 2016 WL 93847, at *1 (D. Del. Jan. 7, 2016). Thus, should the Court decide the issue now, it should adopt Teva's proposed construction and hold claim 12 not indefinite; there is no evidence to support any contrary conclusion.

### L. '808 Patent, Claim 1: "Counter Display Arranged to Indicate Dosage Information"

| Teva's Proposed Construction | Defendants' Proposed Construction |
|---|---|
| Plain and ordinary meaning in view of the claims, specification, and prosecution history.<br><br>"a component of the dose counter that displays information regarding the number of doses remaining" | "structure displaying the number of doses remaining" |

Given its simplicity, this phrase does not require construction. If the Court

disagrees, it should adopt Teva's proposal, which reflects the term's plain and ordinary meaning. Defendants' suggestion that the counter display must provide *specific* information about the number of doses remaining—i.e., the total number of doses remaining—as opposed to any dosage information, is without support.

The '808 Patent uses "information" consistent with its ordinary meaning: data, facts, or knowledge of a particular situation. The claims in the '808 Patent nowhere recite or suggest that a "counter display" must display the *total* number of doses remaining. *See, e.g.*, '808 Patent, claims 1, 2, 4, 27. To be sure, claim 1 requires a dose counter for an inhaler. And, consistent with its plain meaning, a dose counter tracks numerically every dose of a medicament canister dispensed by the inhaler and communicates that information to the patient. These requirements of a dose counter do not mandate, however, that a single "counter display"—a particular component of the dose counter—must relay, among all information about the dosage, the *total* number of doses remaining in a canister.

Defendants identify no evidence of lexicography or disavowal sufficient to depart from this plain meaning. While certain embodiments of the dose counter utilize a single counter display to convey the total number of doses remaining, *see, e.g.*, '808 Patent, 17:5-11, 20:62-21:8, these embodiments do not limit claim scope, as both the specification and Federal Circuit precedent make plain, *id.* at 11:6-10, 21:29-32; *supra* Section III; *Phillips*, 415 F.3d at 1323. Teva "is entitled to the full

scope of [its] claims," not merely a preferred embodiment thereof, as Defendants' construction dictates. *Kara Tech. Inc.*, 582 F.3d at 1347-48.

For words with a "readily apparent" plain meaning, "claim construction . . . involves little more than the application of the widely accepted meaning of commonly understood words." *Phillips*, 415 F.3d at 1314. "Information" is such a term and has a widely understood meaning that is consistent with its use in the '808 Patent. *See id.* (approving reference to general purpose dictionaries in these circumstances); Merriam-Webster's Collegiate Dictionary 641 (11th ed. 2003) ("FACTS, DATA") (Ex. 19).[8] In fact, courts in other patent disputes have similarly defined "information." *See, e.g.*, *Gemstar-TV Guide Int'l, Inc. v. ITC*, 383 F.3d 1352, 1373 (Fed. Cir. 2004) (relying on dictionary to define "information" as "facts or figures ready for communication or use"). Defendants' construction is unsupported by the intrinsic and extrinsic evidence, and it should be rejected.

[8] Merriam-Webster Dictionary 254 (2005) ("knowledge obtained from investigation, study, or instruction: FACTS; DATA") (Ex. 20); Webster's New World College Dictionary 733 (4th ed. 2005) ("knowledge acquired in any manner; facts; data; learning; lore") (Ex. 21); New Oxford American Dictionary 891 (3rd ed. 2012) ("facts provided or learned about something or someone") (Ex. 22); Webster's Third New International Dictionary of the English Language Unabridged 1160 (2002) ("knowledge of a particular event or situation") (Ex. 23).

### M. '808 Patent, Claim 1: "First Station"/"Second Station"

| Teva's Proposed Construction | Defendants' Proposed Construction |
|---|---|
| "first station"<br><br>Plain and ordinary meaning in view of the claims, specification, and prosecution history.<br><br>"a first region" | "first structure on which the counter is located" |
| "second station"<br><br>Plain and ordinary meaning in view of the claims, specification, and prosecution history.<br><br>"a second region" | "second structure, separate from the first structure, to which the counter display is moved" |

The parties dispute whether a "first" and "second" station of the dose counter must be physically separate structures on which the counter display is located. Defendants, in reading a limitation requiring two physically, separate structures into the claims, ignore the claims' clear language and manufacture this requirement out of whole cloth. If the Court decides construction is necessary, it should adopt Teva's proposal.

The claims do not require that the first and second station be separate structures. And the specification expressly states that a "first station may comprise a ***region*** of the dose counter," and that region may be located before a display location, such as a display window, for the counter indicia. '808 Patent, 2:65-67 (emphasis added). This language makes clear that a "station" of the dose counter is

a location or region, not an independent structure.

The claims likewise support Teva's proposed construction. For example, claim 23 provides that the "second shaft . . . is located *at* the second station." Claim 23 thus refers to a structure ("second shaft") located at a region ("second station"), in the same way that one might say the house (a structure) is located at the corner (a location). Were Defendants correct that the term "station" itself referred to a structure (as opposed to a location), then claim 23 would not recite a separate structural element using different language (a second shaft). That the claim does refutes Defendants' proposed construction. *Phillips*, 415 F.3d at 1324-26 (reading claims in context of each other). Claim 1 lacks this or any structural requirement entirely, and Defendants' effort to import one must be rejected.

**N. '512 Patent, Claim 1: "Different Sides"**

| **Teva's Proposed Construction** | **Defendants' Proposed Construction** |
|---|---|
| Plain and ordinary meaning in view of the claims, specification, and prosecution history.<br><br>"not the same side" | "distinct surfaces where each pin/aperture of the chassis connects to a different face of the body" |

The phrase "different sides" does not require construction. The term's meaning is straightforward, as Teva's construction of "not the same side" reflects.

Claim 1 of the '512 Patent requires that "either the pins or the apertures on the chassis are positioned on ***different sides*** of the [dose counter's] chassis." Defendants rewrite this claim language to require that *each* pin/aperture on the chassis interacts

with *different faces of the inhaler body*. This invented requirement appears nowhere in the claim, and nothing in the specification justifies reading it into the claim. *Toshiba*, 681 F.3d at 1369; *Thorner*, 669 F.3d at 1365-66. The claims merely require that the pins or apertures be positioned on different sides of the chassis, not that each pin or aperture attaches to a different face of the body. *See, e.g.*, '512 Patent, claims 1; *id.*, Claim 6 ("the pins or the apertures of the chassis are positioned on three different sides of the *chassis*").

Several figures in the specification undercut Defendants' position. For example, the preferred embodiment illustrated in Figures 6B and 6C show that apertures 188, 190, 192 are formed on three different sides of the chassis.

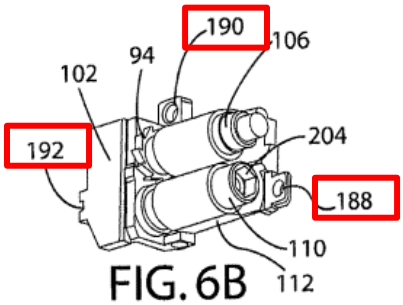


FIG. 6B

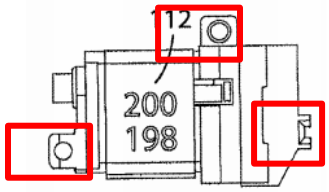
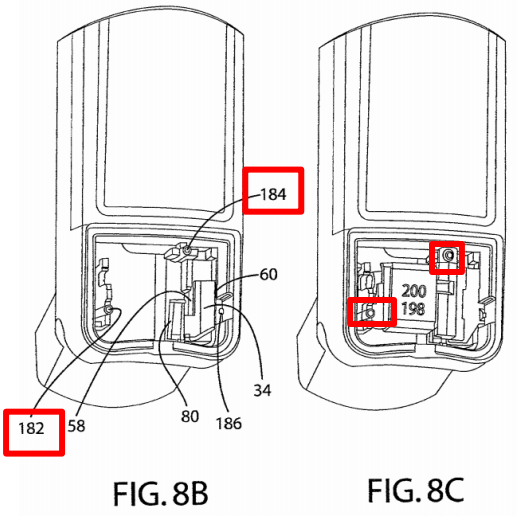


FIG. 6C

'512 Patent, Figs. 6B, 6C (boxes added); *see also id.* at 16:55-62 (description). Notably, in this embodiment the apertures are on the chassis, and they connect with the pins on the main body.

And Figures 8B and 8C show that two pins (182 and 184) on the inhaler are located on the same face of the body, contrary to Defendants' proposal.




'512 Patent, Figs. 8B, 8C (boxes added). Defendants' construction, which would have *each* of the apertures on the chassis connect to different faces of the body, would exclude this preferred embodiment, in which more than one pin/aperture on the chassis connects to the same face of the body. But nothing in the specification supports that requirement, which is plainly absent from the claim language. Defendants' construction is therefore flawed. *See, e.g.*, *Epos Techs. Ltd. v. Pegasus Techs. Ltd.*, 766 F.3d 1338, 1347 (Fed. Cir. 2004) ("[A] claim construction that excludes a preferred embodiment . . . is rarely, if ever correct and would require highly persuasive support.").

### O. '512 Patent, Claim 2: "Formed in the Body"

| Teva's Proposed Construction | Defendants' Proposed Construction |
|---|---|
| Plain and ordinary meaning in view of the claims, specification, and prosecution history.<br><br>"located in the body" | "an integrated part of the body" |

Defendants again seek to import limitations into the asserted claims via claim language that is plain on its face. Defendants contend that claim 2's requirement for a "dose counter chamber that is formed in the body" requires a dose counter chamber that is an "integrated part of the body." During conferral, Defendants stated that the dose counter chamber must be "formed by the body"—i.e., created by the walls of the inhaler. Nothing in the '512 Patent compels or even suggests such a construction. Defendants' position should be rejected, and the Court should adopt Teva's proposal if it believes construction is necessary.

Claim 2 of the '512 Patent does not require that the dose counter chamber be an integral part of the body of the inhaler. Defendants' proposal, in effect, rewrites the claim by changing the locational requirement "***formed in*** the body" to the compositional requirement "***created by*** the body." "[F]ormed in the body" merely indicates that the dose counter chamber has to be located inside, rather than outside of the body of the inhaler. It does not impose any additional restrictions on how the dose counter chamber was made, what structures form the boundaries of the chamber, etc. Teva's simple construction is consistent with this plain meaning.

Teva's construction is also consistent with the only two times the phrase "formed in" appears in the specification. In the first instance, the term describes the orientation of a projection on a flexible leg (or fork) on a shaft—i.e., outwardly facing. *See* '512 Patent, 3:18-20 ("Each leg may have at least one said projection

formed in an outwardly facing direction thereon."). Defendants' construction would render this passage nonsensical. Under their proposal, the projection on the shaft would need to be an "integrated" part of an "outwardly facing direction." Plainly, that is not what the term "formed in" conveys. The same is true where the specification states that an "end stop 70 [is] formed in the dose counter chamber." *Id.* at 12:48-49. Indeed, Figure 8A, which shows the end stop, does not suggest that the end stop (70) is integral with the structure of the counter chamber (66). To the contrary, and consistent with the meaning of "formed in" in the context of the specification (and Teva's construction), Figure 8A merely illustrates that the end (70) stop is located in the counter chamber (66).

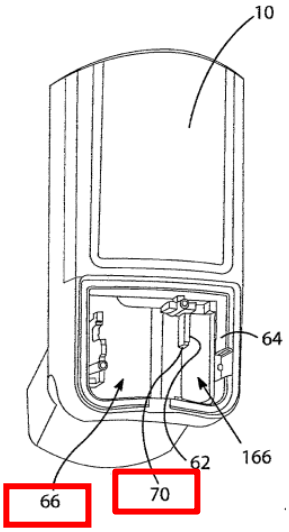



FIG. 8A

'512 Patent, Fig. 8A (boxes added).

To the extent Defendants attempt to rely on dictionary definitions of "formed"

and "in," they run headlong into contrary precedent. The Federal Circuit has cautioned against "elevating the dictionary to such prominence . . . that it focuses the inquiry on the abstract meaning of words rather than on the meaning of claim terms within the context of the patent." *Phillips*, 415 F.3d at 1321. Although dictionaries can aid in understanding the ordinary and customary meaning of a term, they cannot be used to contradict the intrinsic record. *Id.*

## V. Conclusion

For the foregoing reasons, the Court should adopt Teva's proposed constructions of the disputed claim terms and reject the Defendants' proposals.

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